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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-------------------------|---------------------|------------------|
| 10/024,574 | 12/21/2001 | Avinash Prahalad Sattur | 4062-11 | 2460 |

7590 09/17/2003

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/024,574 | SATTUR ET AL. |
| Examiner | Art Unit | |
| Dr. Kallash C. Srivastava | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the reply is filed after the period specified above, a timely reply will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 December 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) is/are withdrawn from consideration.

5) Claim(s) is/are allowed.

6) Claim(s) is/are rejected.

7) Claim(s) is/are objected to.

8) Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) .

4) Interview Summary (PTO-413) Paper No(s).
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

1. Claims 1-15 are pending.

Election /Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Group I, consisting of claims 1-5 drawn to a composition comprising an aldose reductase inhibitor, classified under Class 435, subclass 189, for example.
 - Group II, consisting of claims 6-12 drawn to a method to make an aldose reductase inhibitor, classified under Class 435, subclass 69.2, for example.
 - Group III, consisting of claims 13-15 drawn to another method to make a pharmaceutical composition comprising an aldose reductase inhibitor, classified under Class 435, subclass 41, for example.
3. The inventions are distinct, each from the other because of the following reasons:

Inventions In Group I is related to inventions in Groups II - III as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, for e.g., the method of Group II to prepare said enzyme inhibitor is applicable to prepare a variety of industrial compounds (e.g., citric acid, antibiotics) and enzymes (e.g., alpha amylase). Similarly, the composition claimed in Inventions of Group I may also be prepared by different methods, for example chemical synthesis without microbial fermentation.

Inventions in Groups II and III are unrelated to each other because they are directed to different inventions that are not connected in design, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example inventions disclosed in claims encompassing invention in Group II are directed to a method to obtain a compound through fungal fermentation, wherein said compound is an inhibitor of an enzyme. Invention encompassing claims in group III is a method to make a pharmaceutical composition, wherein said composition comprises an enzyme inhibitor. Thus, inventions in Groups II and III do not share the same design, process steps to obtain two different compositions and the effects of those compositions.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require

independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon cancellation of claims to a non-elected invention, inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

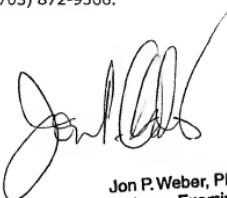
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Daylight Saving, or Standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9306.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703)-605-1196
September 15, 2003



Jon P. Weber, Ph.D.
Primary Examiner